

U.S. DISTRICT COURT LIFTS INJUNCTION.

DoD RESUMES ANTHRAX VACCINATIONS.

FDA RULES ANTHRAX VACCINE PROTECTIVE REGARDLESS OF ROUTE.

8 Jan 04

POLICY

What is DoD's current anthrax vaccination policy?

As of 7 January 2004, anthrax vaccinations in the Department of Defense have resumed, at the direction of the Deputy Secretary of Defense.

On 7 January 2004, the U.S. District Court for the District of Columbia granted a motion to stay an injunction against anthrax vaccinations in place since 22 Dec 03. This court action lifts the injunction and permits troops once again to be protected against the lethal bioweapon anthrax.

Anthrax vaccinations on hold since 23 December 2003 will now resume. Troops will be vaccinated where they left off. No one need resume the vaccination series from the beginning. Throughout this process, the Anthrax Vaccine Immunization Program (AVIP) was never cancelled.

How did the injunction get lifted?

The Department of Justice filed a motion with the U.S. District Court, requesting a stay. On 7 Jan 04, Judge Sullivan agreed to stay the injunction, thus allowing for resumption of the DoD Anthrax Vaccine Immunization Program (AVIP).

The stay is for an indefinite period of time. Although the litigation has not been finally resolved, DoD remains convinced that the AVIP complies with all legal requirements and there is now no judicial restraint on AVIP implementation. Therefore, senior civilian leaders in DoD have directed the immediate resumption of vaccinations.

Where did the injunction come from?

On 22 Dec 03, the United States District Court for the District of Columbia issued a preliminary injunction against the current operation of the AVIP. Safety of the vaccine was not the focus of the injunction. The judge ruled based on concerns about the completeness of the Food and Drug Administration's (FDA) process to approve the vaccine for use against inhalational anthrax.

What is FDA's position about the effectiveness of anthrax vaccine?

For years, FDA has held that anthrax vaccine prevents anthrax, regardless of the route of exposure. On 30 Dec 03, the FDA codified this position in a "Final Rule and Order" that was published in the *Federal Register* ("the government's newspaper") on 5 Jan 04. The FDA press release appears at: www.fda.gov/bbs/topics/NEWS/2003/NEW01001.html. The full text of the FDA final rule appears at www.access.gpo.gov/su_docs/fedreg/a040105c.html.

What did DoD and the Department of Justice (DoJ) do in response to the court injunction?

The Department of Justice (DoJ) represented the DoD, the Department of Health & Human Services (HHS), and the Food & Drug Administration (FDA) in this case. DoJ filed several motions with the U.S. District Court for the District of Columbia to clarify, lift, or stay the injunction against anthrax vaccinations.

Questions regarding the litigation itself should be addressed to the Department of Justice.

Why is resuming anthrax vaccinations so important?

DoD is committed to protecting American troops and knows that anthrax vaccinations provide the best protection against a lethal weapon. Anthrax vaccinations are the best round-the-clock measure to protect our troops.

Why didn't you allow personnel to choose voluntarily to be vaccinated against anthrax?

The implications of the judge's order precluded anthrax vaccinations except under the extremely detailed and time-consuming requirements of the FDA's "investigational new drug" provisions. DoD is not using anthrax vaccine as an investigational drug.

The Department's vaccine programs protect personnel at high risk and afford the military the ability to continue mission critical duties. There can be no individual choice; individual protective measures including vaccinations serve to support the entire force.)

When did anthrax vaccinations resume after the injunction was lifted?

Vaccinations resumed after Dr. Chu signed the memo on 7 January 2004.

What about all those people who received anthrax vaccinations in the past? Do they have to start the six-dose series from the beginning?

No. Prior doses count. One resumes vaccination where you left off.

What happens to people whose regularly scheduled dose was delayed?

Each dose of anthrax vaccine is like walking up a set a stairs. You may remain on one step longer than originally planned, but the next dose of vaccine will resume development of protective immunity (climbing further up the stair case).

There is no reason for concern that interrupting the anthrax vaccination series causes any harm. The concern is that immunity did not increase because of delayed doses. When one resumes the anthrax vaccination series (when you get your next dose), published evidence shows that the body has a good immune memory and will have a good antibody response.

Resume anthrax vaccination in accordance with the FDA-licensed schedule (0, 2, 4 weeks, 6, 12, 18 months, annual boosters). Do not restart the series. Do not skip or repeat any doses in the series. Continue vaccinations until the six shot series is completed, followed by an annual booster. Please ensure all vaccinations are accurately recorded in the medical record and the appropriate electronic immunization tracking system.

How many servicemembers have been vaccinated?

DoD has vaccinated over 1 million service members since the beginning of the AVIP program in March 1998 with more than 3.7 million doses of anthrax vaccine. Since June 2002, we have given over 625,000 service members more than 1.6 million doses of anthrax vaccine.

Does DoD experiment on service members or use them as “guinea pigs”?

Absolutely not. The purpose of military vaccination programs is to keep our troops healthy and help them return home safely.

COURT CASE

What was the court ruling regarding anthrax vaccinations?

Six anonymous men and women are suing the Secretaries of Defense and Health & Human Services (HHS) and the Commissioner of Food & Drugs in the U.S. District Court for the District of Columbia. The six allege anthrax vaccine is an investigational new drug (IND) according to Title 10 United States Code section 1107, necessitating informed consent before vaccination. DoD, HHS, and FDA respond that the FDA has determined that because the approved label is nonspecific as to route of exposure to anthrax spores, it includes inhalation exposure; consequently, informed consent is not required. On December 22, 2003, Judge Emmet G. Sullivan ordered a preliminary injunction. He wrote: “In the absence of a presidential waiver [of informed consent], defendants [DoD, HHS, FDA] are enjoined from inoculating service members without their consent...” The judge stayed his injunction on January 7, 2004.

Did the Department of Defense comply with Judge Sullivan’s injunction?

Yes, promptly.

What was the basis of the 22 Dec 03 injunction?

The District Court ruling questioned the legal status of anthrax vaccine when used to protect individuals against inhalational anthrax. Safety of the vaccine is not the focus of the ruling.

For years, FDA has held that anthrax vaccine prevents anthrax, regardless of the route of exposure. On 30 Dec 03, the FDA codified this position in a "Final Rule and Order" that was published in the *Federal Register* ("the government's newspaper") on 5 Jan 04. The FDA press release appears at: www.fda.gov/bbs/topics/NEWS/2003/NEW01001.html. The full text of the FDA final rule appears at www.access.gpo.gov/su_docs/fedreg/a040105c.html.

MILITARY JUSTICE

What happens to those individuals who were court-martialed or given non-judicial punishment before the injunction for refusing to take anthrax vaccine?

This is a matter for appeals processes and the Board for the Correction of Military (or Naval) Records.

How common are refusals of anthrax vaccination?

Since inhalational anthrax spread by terrorists in fall 2001 killed five people in the United States, very few people in DoD have refused anthrax vaccination. About ten people have been separated from military service related to refusal of vaccination from 2001 through 2003.

How will anthrax-vaccine refusals be handled now that the injunction is lifted?

The same way as before the injunction was put in place.

DoD begins by assuming that someone refusing anthrax vaccine is not aware of the science that provides the foundation for the vaccine's safety and effectiveness. So, our first action with those who might refuse the vaccine will be to determine their concern and provide information about the deadly effects of anthrax spores and the protection afforded by the vaccine. Someone refusing vaccination is reeducated by a healthcare professional, counseled about the career implications of refusing a lawful order, provided multiple opportunities to ask questions, and provided legal counsel.

We anticipate that very few service members will refuse to be vaccinated, given the clearly lethal effects of anthrax spores and the FDA's clear statements about the safety and effectiveness of vaccination.

This is a force protection issue. If a service member continues to refuse the vaccine, then a commander will manage the situation as he or she would for any failure to obey a lawful order, including educating the member about the AVIP as appropriate. Military and other civilian judges consistently have found orders for members to be vaccinated to be lawful orders.

We expect service members to comply with administration of this vaccine as for any other mandatory vaccination. It is comparable to an order to wear body armor during armed engagement, or to don a protective mask in a suspected chemically or biologically contaminated environment. Any service member who does not comply with these measures endangers his/her own health, and places both their unit and mission accomplishment at risk.

PROTECTION

What is the threat of anthrax used against our military?

Anthrax is an attractive weapon of mass destruction for our enemies. It is highly lethal, relatively easy to produce in large quantities and to develop as a weapon, easily spread in the air over a large area and it can be stored and remain dangerous for a long time. For this reason, anthrax may be the most important biological warfare threat facing U.S. forces.

The intelligence community believes several countries currently have or are developing an offensive biological warfare capability using anthrax. Given the ease with which anthrax can be produced, U.S. forces may have little or no warning before an anthrax attack, which could be delivered by unconventional means.

How did DoD ensure people were protected against weaponized anthrax during the interruption in vaccinations?

DoD is concerned about the health and safety of all service members, including those assigned or deployed in high threat areas. That is why we paid careful attention to other pillars of Force Protection, including protective masks and suits, detection equipment, ongoing surveillance and intelligence gathering and stockpiling antibiotics in the event of exposure.

Why doesn't DoD use antibiotics rather than anthrax vaccine?

There is no better round-the-clock protection against anthrax infection than the anthrax vaccine. Antibiotics are effective when started immediately or very soon after exposure. However, not all exposures can be predicted in advance or even recognized in very early stages, particularly in certain military situations. Antibiotics cannot be used for long periods of time before a biological attack, because antibiotics have a known set of adverse reactions.

Other protective measures exist, but do not offer the advantages of vaccination. Detection devices do not deliver warnings fast enough, nor are there enough of them, to prevent exposure to anthrax spores. Protective equipment (e.g., impermeable suits, masks, "Mission Oriented Protective Posture," MOPP) can shield people from anthrax spores for several hours, but such equipment is too cumbersome to be used for prolonged periods of time.

Does anthrax vaccine protect people against inhalational anthrax?

Yes. The DoD shares the repeated findings of the FDA, the National Academy of Sciences, and numerous other authoritative experts that anthrax vaccine is effective against inhalational anthrax.

In a report commissioned by the United States Congress, the National Academy of Sciences' Institute of Medicine concluded in March 2002 that anthrax vaccine is "an effective vaccine for the protection of humans against anthrax, including inhalational anthrax, caused by all known or plausible engineered strains of *Bacillus anthracis*."

Is anthrax vaccine safe?

Yes. The DoD shares the repeated findings of the FDA, the National Academy of Sciences, and numerous other authoritative experts that anthrax vaccine is safe.

For details see: www.fda.gov/bbs/topics/NEWS/2003/NEW01001.html or www.access.gpo.gov/su_docs/fedreg/a040105c.html.